DEPARTMENT OF HEALTH & HUMAN SERVICES

94373d

Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

October 23, 2003

Ref: 2004-DAL-WL-05

WARNING LETTER

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Mr. Jimmy J. Girouard
President
Colon Therapeutics, Inc.
2909 Main Avenue
Groves, Texas 77619

RE: Jimmy John III
Colonic Irrigation System

Dear Mr. Girouard:

During the Food and Drug Administration's (FDA's) inspection of Colon Therapeutics, Inc., located in Groves, Texas, on December 12, 2002, and January 22, 2003, we determined that your establishment manufactures the Jimmy John III colonic irrigation systems and rectal nozzles and markets these products in the United States. These products are devices as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h).

A review of records collected during the inspection and information posted on your website at http://www.colontherapeuticsinc.com revealed that your colonic irrigation products are a system consisting of a rectal nozzle, a water tank, flow controller, temperature indicator and alarm, ultraviolet lamp, water filter, and a series of valves and pipes. This configuration is consistent with the type of device defined in Title 21, Code of Federal Regulations (CFR), Section 876.5220 (colonic irrigation system). Your colonic irrigation devices do not meet the definition of enema kits which are classified in 21 CFR 876.5210, which definition expressly excludes colonic irrigations systems.

Our records indicate that you received FDA premarketing clearance to market these products for colon cleansing when medically indicated under the supervision of a practioner, such as before radiological or endoscopic examinations. When FDA cleared the 510(k)s for the Jimmy John rectal nozzles, an accessory of the Jimmy John colonic irrigation system, we indicated that our clearance was limited to prescription use only. See K973256 and K972455 for the two types of rectal nozzles for which you received premarketing clearance in September, 1997. Both the colonic irrigation systems and the rectal nozzles were cleared for the same intended use as defined in 21 CFR 876.5220. A prescription device is one "which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which 'adequate directions for use' cannot be prepared." 21 CFR 801.109. Prescription devices are exempt from the requirement in section 502(f)(1) of the Act, 21 U.S.C. § 352(f)(1) – that they bear adequate directions for use – if, among other things, their labels bear the statement: "'Caution: Federal law restricts this device to sale by or on the order of a ____,' the blank to be filled in with the word 'physician,' 'dentist,' 'veterinarian,' or with the description designation of any other practitioner licensed by the law of the State in which he practices to use and order the use of the device." 21 CFR 801.109(b)(1). Your colonic irrigation systems fail to bear the prescription legend, and therefore, are misbranded under section 502(c) of the Act, 21 U.S.C. § 352(c). Your devices are also misbranded under section 502(f)(1) of the Act, 21 U.S.C. § 352(f)(1), because their labeling fails to bear adequate directions for their intended use.

We remind you that the clearance you have for the Jimmy John III Colonic Irrigation Systems covers their use for colon cleansing when medically indicated under the supervision of a practitioner. Any therapeutic claims that you make for these products that exceed this cleared intended use would make the products class III devices, which require the submission and approval of an application for premarket approval (PMA) before they may be legally marketed. See 21 CFR 876.5220(b)(2). The kind of information you need to submit in order to obtain this premarket approval is described on FDA's device website at www.fda.gov/cdrh/devadvice.

FDA also discovered during the inspection that your firm possessed information that reasonably suggested that the Jimmy John III may have caused or contributed to the perforation of a patient's bowel. We have reviewed your written response of February 22, 2003, which included records regarding this adverse event. The information you submitted does not rule out our presumption that the use of your colonic irrigation system and rectal nozzle may have been a factor in the adverse incident because: (a) a surgical intervention was required to repair the patient's perforated sigmoid colon following a colonic irrigation

procedure at a Dallas health facility earlier in the day; (b) there were no other devices, other than your devices involved in the colonic irrigation procedures; (c) your colonic irrigation systems were distributed without a prescription legend on their labeling; (d) the colonic irrigation procedure was administered for conditions such as bad gas and bad breath, without the adequate supervision of a licensed medical practitioner; (e) none of the responsible staff who treated the patient at the health facility was a licensed medical practitioner; (f) the responsible staff could not confirm or remember the patient's prior medical conditions (constipation or bowel problems or prior colonoscopy) that may have been considered contraindications; (g) there was no evidence that the patient engaged in certain activities or ate certain foods that may have caused gas and bloating after the colonic irrigation procedure; and (h) you and/or the responsible staff at the Dallas health facility could not determine or confirm whether the patient had experienced a perforated colon during a prior colonoscopy that may have been considered a condition of contraindication. Accordingly, under the Medical Device Reporting (MDR) regulation, 21 CFR 803.50, you were required to file a report with FDA of this adverse event within 30 days of becoming aware of the incident. Your failure to file an MDR causes the Jimmy John colonic irrigation devices to be misbranded under section 502(t) of the Act, 21 U.S.C. § 352(t).

We have reviewed your modified MDR procedures (SOP 05-03) and have found that they are still deficient as follows:

1. Section 4.1 does not include "death" as one of the MDR-reportable events as required under 21 CFR 803.50(a)(1); and
2. Section 4.2 does not call for your firm to "evaluate the cause" of the problem as required under 21 CFR 803.50(b)(2).

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you receive this letter what steps you are taking to correct the problems. Also, please explain how you plan to prevent these violations from happening again. If you need more time to respond, let us know why and when you expect to complete your correction. Please direct your response to Thao Ta, Compliance Officer, HFR-

SW140, Food and Drug Administration, 4040 North Central Expressway, Suite 300, Dallas, Texas 75204.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains to some of the requirements applicable to your device, but does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers, International and Consumer Assistance at 1-800-638-2041 or through the Internet at http://www.fda.gov.

Sincerely,

Michael A. Chappell
Dallas District Director

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